



Cell Banking

Investing in GMP-Compliant
Manufacturing of
Biopharmaceuticals

*If you can't do it right the first time,
then don't do it at all....*

- ✦ The quality of biopharmaceuticals depends on the quality of cells used for production.
- Cross-contamination with another cell line
- Contamination with bacteria, fungi, virus
- Identity and integrity of expression construct of recombinant cell lines.

Who's being protected from What?

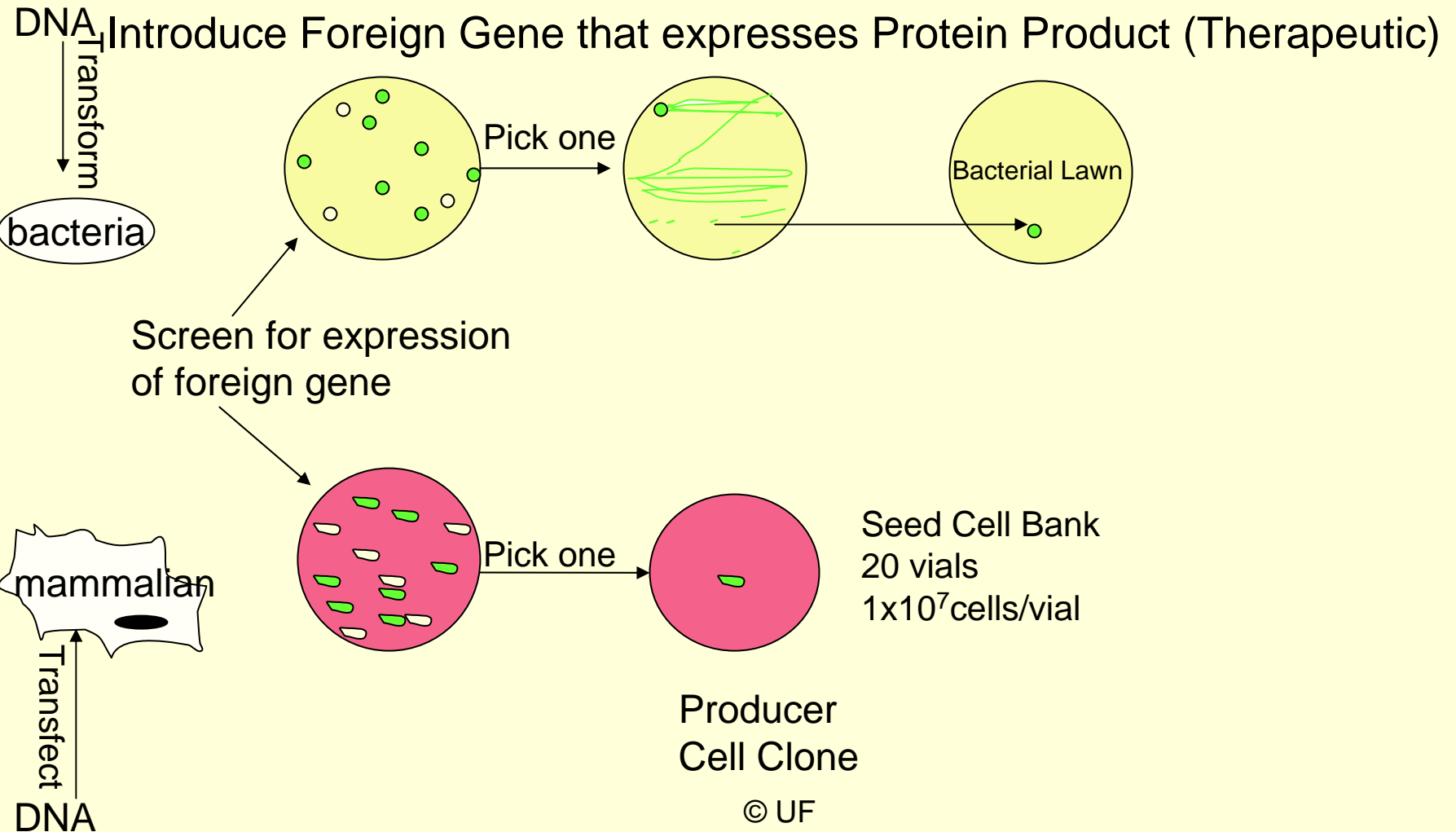


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Center of Excellence for Regenerative Health Biotechnology

Building the Bank

Transformation or Transfection



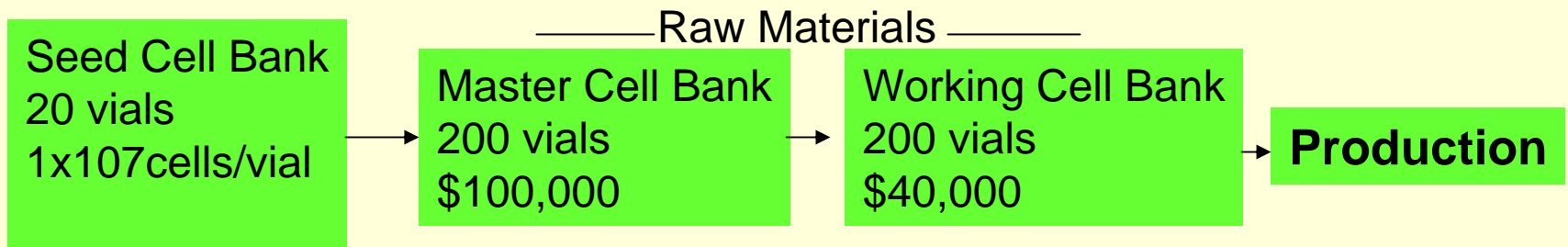
Master Cell Bank

- **A well characterized cell bank in accordance with regulatory standards (21 CFR 610)**
- **Master cell bank established from single clone**
- **Quality established from master bank to production and end-of-production cells**
- **Master cell bank represents a cell reserve ‘frozen-in-time’**
 - **Preserves characteristics**
 - **Prevents contamination and deterioration**

GMP Manufacturing

Master Cell Bank & Working Cell Bank

A two tiered frozen cell bank



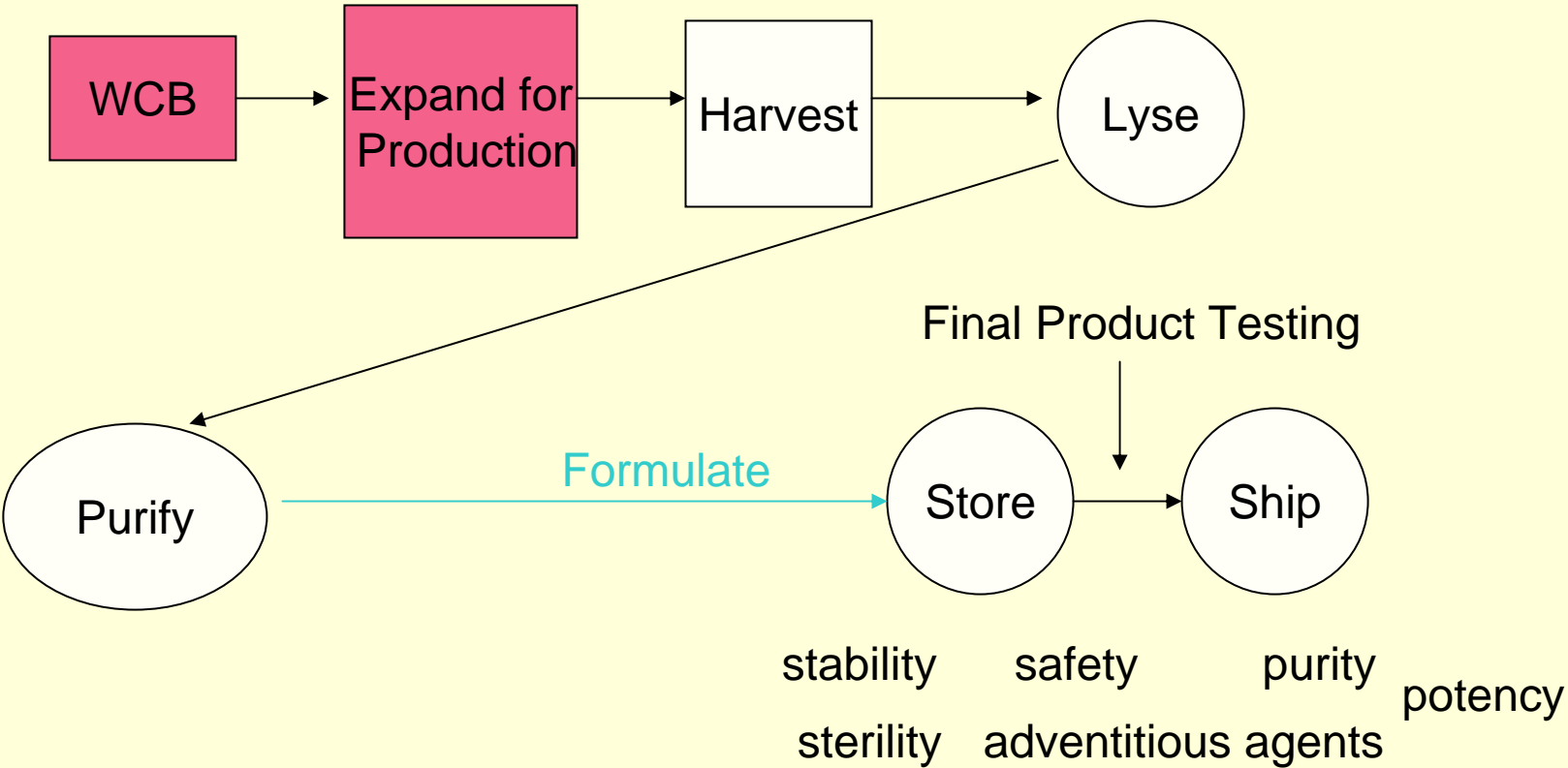
- Working cell bank: cells from one vial of the master bank which have been grown for several passages before storage.
- When future cells are needed, they are taken from the working cell bank.
- The Master cell bank is used only when absolutely necessary, ensuring a stock of cells with a low passage number to avoid genetic variation within the cell culture.
- Stored in two or more locations. One is off-site.

Characterization of Master Cell Bank

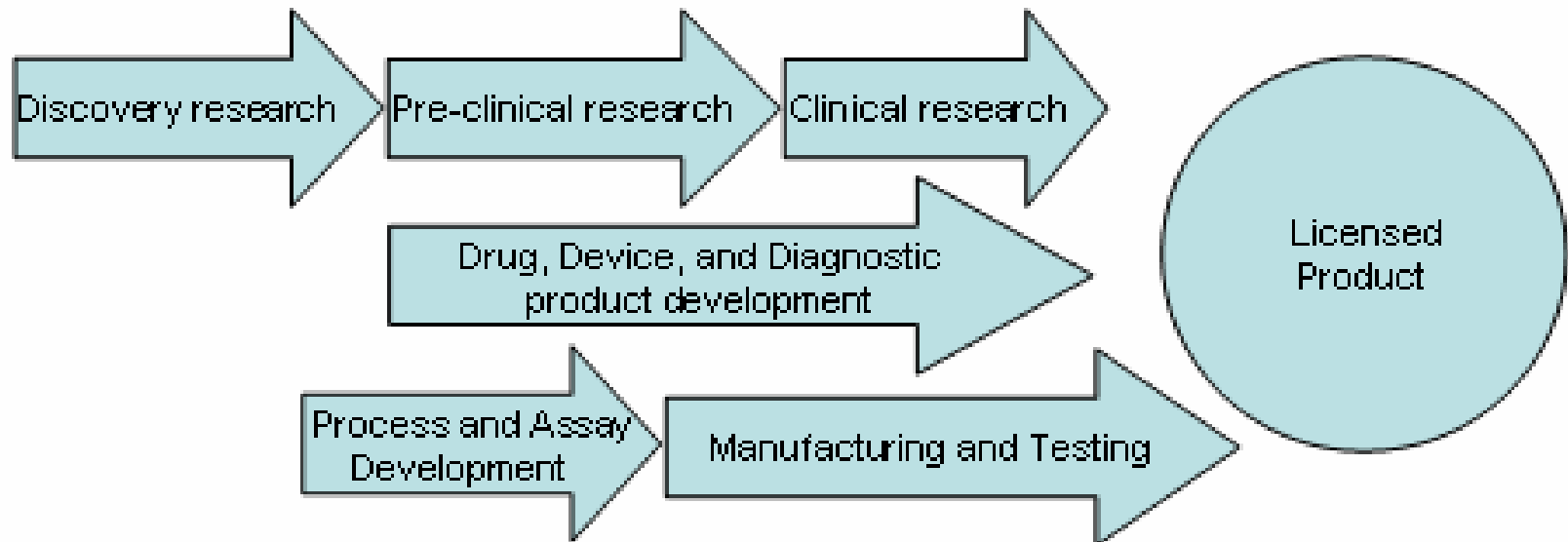
Confirmation of:

- 1) Identity – Cells and their expression construct are what they are intended to be.
- 2) Purity – Test for the presence of contaminating cell lines, viruses, mycoplasma, and bacteria.
- 3) Stability – Cell viability and stability of coding region (for recombinant cell banks) must be determined during cultivation and storage.

Production Process



Product Pathway



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